iHealth® COVID-19 Antigen Rapid Test

Healthcare Provider Instructions for Use

Model: ICO-3000/ICO-3001/ICO-3002

For use with anterior nasal swab specimens
For in vitro Diagnostic Use
This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA)

INTENDED USE

The iHealth® COVID-19 Antigen Rapid Test is lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first seven (7) days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. This test can be performed with or without the supervision of a telehealth proctor.

The iHealth® COVID-19 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definitive cause of disease. Individuals who test positive with the iHealth® COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures, such as isolating from others and wearing a mask. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with

COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care or by following the mobile application instructions for self-reporting. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The iHealth® COVID-19 Antigen Rapid Test is intended for non-prescription self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

The iHealth® COVID-19 Antigen Rapid Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

PRODUCT DESCRIPTION

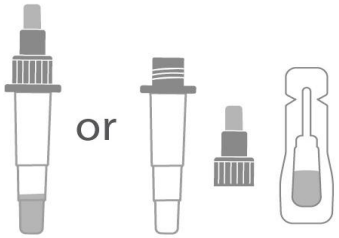
The iHealth® COVID-19 Antigen Rapid Test requires the following elements for operation.

Materials provided in the Test Kit:

Kit components	Quantity					
	1 test Kit	**2 tests Kit**	**4 tests Kit**	**5 tests Kit**	**6 tests Kit**	**40 tests Kit**
COVID-19 Test Card(s)	1 ea/box	2 ea/box	4 ea/box	5 ea/box	6 ea/box	40 ea/box
Nasal Swab(s)	1 ea/box	2 ea/box	4 ea/box	5 ea/box	6 ea/box	40 ea/box
Tube(s)	1 ea/box	2 ea/box	4 ea/box	5 ea/box	6 ea/box	40 ea/box
Lay User Instruction for Use	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box	1 ea/box

For Healthcare Provider Instructions for Use, please see the company website: https://www.ihealthlabs.com

COVID-19 Test Card(s)



Tube(s) pre-filled or empty Tube(s) with sealed Solution(s)

Swab(s)

iHealth® COVID-19 Antigen Rapid Test components

Materials required but are not provided in the kit:

- Smartphone (supplied by the user. iOS 12 or above. android 6.0 or above)
- User is required to download the “iHealth COVID-19 Antigen Rapid Test” App for iOS or Android phones. Email address and internet connection is required to use the App. User should follow the step-by-step instructions in-app to complete the test.
- Timer

PRINCIPLE OF PROCEDURES

The iHealth® COVID-19 Antigen Rapid Test employs lateral flow immunoassay technology. Using this test allows for the rapid detection of nucleocapsid protein from SARS-CoV-2.

To begin the test, a self-collected anterior nares swab samples in individuals aged 15 and older or individuals between the age of 2 to 14 with a swab collected by a parent or guardian is inserted into the Tube. The liquid in tube interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The liquid in tube now containing the specimen is added to the Sample Port of the COVID-19 Test Card.

If the extracted specimen contains SARS-CoV-2 antigens, a pink-to-purple T Line, along with a pink-to-purple C Line will appear on the COVID-19 Test Card indicating a positive result. If SARS-CoV-2 antigens are not present, or present at very low levels, only a pink-to-purple C Line will appear.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- An anterior nasal swab sample can be self-collected by an individual age 15 years and older. Children age 2 to 14 years should be tested by an adult.
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- Do not use on anyone under 2 years of age.
- Do not use on anyone who is prone to nosebleeds or has had facial or head injury/surgery in the last 6 months.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Insert the swab into the tube right after taking the sample.
- Test samples immediately after collection, but no more than 4 hours after specimen collection before placement into extraction buffer or up to 2 hours after placement into extraction buffer, if kept at room temperature.
- Once opened, the test card should be used within 60 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your eyes or mouth. Do not ingest any kit components.
- The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose,or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name	Harms (GHS Code) for each ingredient	Concentration
Triton X-100/9002-93-1	Harmful if swallowed (H302) Cause skin irritation(H315) Cause serious eye damage(H318)	0.1%
ProClin® 300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction (H317)	0.05%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19.
- This test has not been validated for use with a video camera and faint bands may not be visible to a telehealth proctor due to differences between cameras.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between May, 2021 and October, 2021. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- False negative results may occur in individuals who have indicated or whose clinical status or history would indicate they are currently taking high doses of biotin. Biotin levels of 1 μg/mL and greater have been demonstrated to result in false negative test results

STORAGE CONDITIONS

Store iHealth® COVID-19 Antigen Rapid Test in a dry location between 36-86 °F (2-30 °C). Ensure all test components are at room temperature 65-86 °F (18-30 °C) before use. It is stable until the expiration date marked on the packaging

For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

QUALITY CONTROL

A procedural internal control is built in the “control line (c)” of the device and is used to ensure that the applied specimen has migrated well into the device. It is coated with goat anti-rabbit IgG and a red colored line should appear after sample was added.

TEST PROCEDURE

Download App: Scan the QR code (below) to download the “iHealth COVID-19 Antigen Rapid Test” App through your Smartphone (iOS12.0+, Android 6.0+). For a full list of compatible smartphone visit: https://ihealthlabs.com/pages/support-ICO3000

Register and Log Into The App

Watch Video in App: Each step has a corresponding instructional video in the App. Watch the video and perform the test according to the instructions.

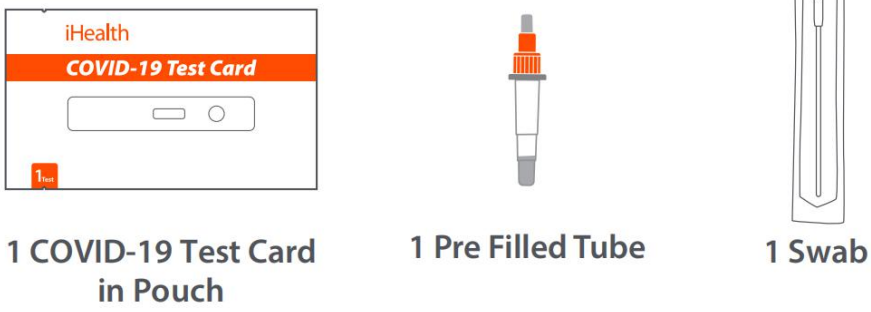
Instructions

The instructions provided here include all the steps of the test. Specific, detailed video instructions on how to perform this test are in the “iHealth COVID-19 Antigen Rapid Test” App.

1) Prepare Materials

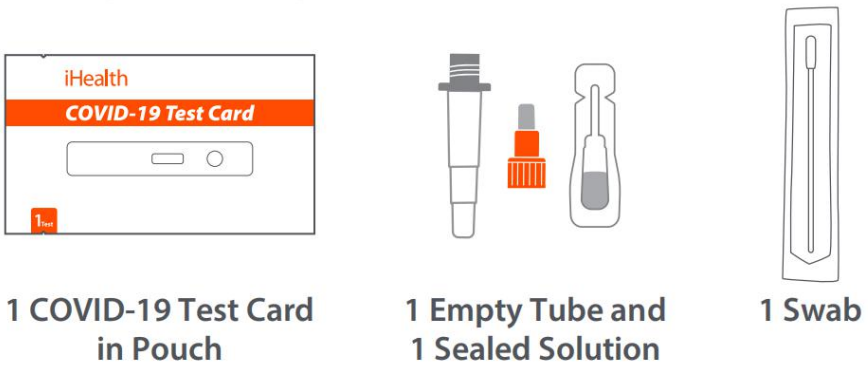
You may have Test Set 1 **OR** Test Set 2 in the package. Please follow proper steps based on the specific set you received.

- ***Test Set 1:*** Open the package, take out the COVID-19 Test Card in Pouch, the Tube pre-filled with the extraction solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.

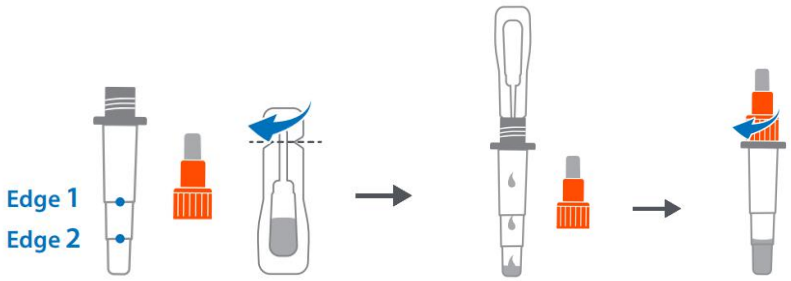


Please go directly to **Step 2 Collect Sample.**

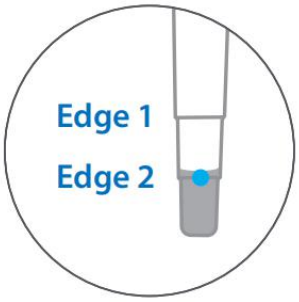
- ***Test Set 2:*** Open the package, take out the COVID-19 Test Card in Pouch, empty Tube, sealed Solution and the Swab. When you are ready to proceed with the test, open the foil pouch of the COVID-19 Test Card.



Please look carefully, there are **two Edges** on the empty tube. Then squeeze **the** sealed solution completely into **the** empty tube.



Please confirm the liquid level with or above Edge 2, then go to **Step 2 Collect Sample**.

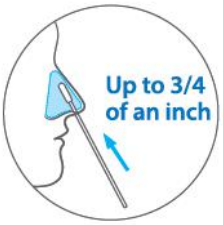


NOTE:
It is acceptable if the liquid level is above Edge 2. However, please do not proceed with this test, if the liquid level is below Edge 2, as this may result in false or invalid results.

2) Collect Sample

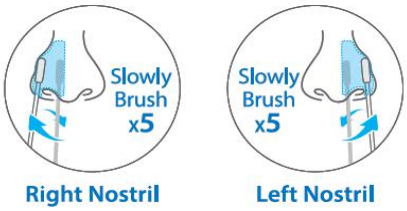
1. Remove the swab from its package, being careful not to touch the tip of the swab. Please keep the swab package for later use.

2. Gently insert the entire absorbent tip of the swab (usually 1/2 to 3/4 of an inch) into your nostril.



Note: With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child's head while swabbing.

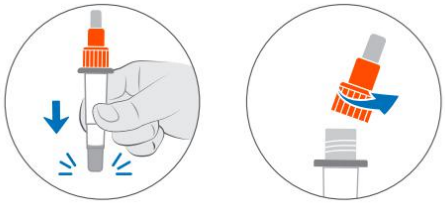
3. Firmly and slowly brush against insides of nostril in a circular motion against the nasal wall at least 5 times. Using the same swab, repeat the same sample collection procedure for the other nostril. Take at least 15 seconds to collect the specimen and be sure to collect any nasal drainage on the swab. Be sure to brush BOTH nostrils with the **SAME SWAB.**



Note: Failure to swab properly may cause false negative results.

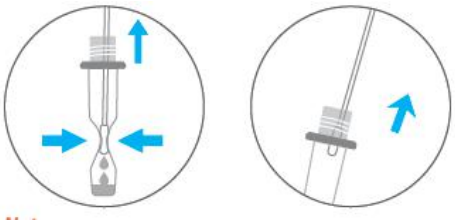
3) Process Sample

1. Tap the tube vertically on the table and twist the large orange cap to open the tube.



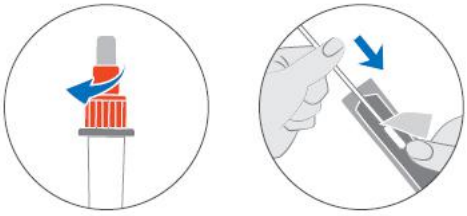
2. Insert the swab into the tube, touch the bottom of the tube with the swab tip, and stir at least 15 times.

3. Squeeze the sides of the tube to express as much liquid as possible from the swab, and then remove the swab.



Note: If you don't squeeze the swab, there may not be sufficient sample material to perform the test properly (i.e., potentially resulting in a false negative result).

4. Screw back the large orange cap, put the swab back into the package. Safely dispose of the swab and the package.



4) Add Sample

Twist to open the small white cap of the tube. Add 3 drops of sample to the Sample Port of the COVID-19 Test Card. Screw back the small white cap.

Note: A false negative or invalid result may occur if too little solution is added to the test card.

5) Wait 15 minutes

Start the timer by clicking the “Start Timer” button on the App, immediately after adding sample to the Sample Port. The result will be ready in 15 minutes.

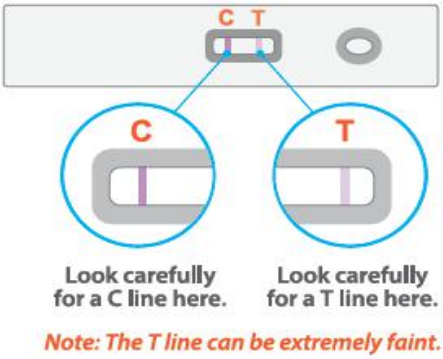
Note: DO NOT interpret your test result until after your 15-min timer has completed, as the T line may take as long as 15 minutes to appear.

6) Read Result

Results should not be read after 30 minutes.

Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes

Result shown at 2x.



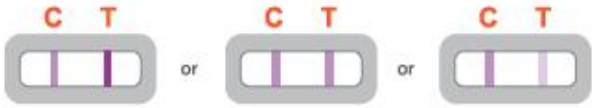
7) Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)



If the Control (C) line and the Test (T) line are visible, the test is positive.

Below are photos of actual positive tests. Any faint visible pink-to-purple test (T) line with the control line (C) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the iHealth® COVID-19 Antigen Rapid Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- Test again in 48 hours if the individual has symptoms on the first day of testing.
- Test 2 more times at least 48 hours apart if the individual does not have symptoms on

the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

Invalid

If the control (C) line is not visible, the test is invalid. **Re-test with a new swab and new test kit.** An invalid result does not indicate if the individual did or did not have COVID-19 and should be repeated.

8) Dispose the Test Kit
After test is completed, dispose of all kit components in trash.

9) Report Test Result
Report the result following the App instructions or share your test result with your healthcare provider.

CLINICAL PERFORMANCE

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC

rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.
Performance of the antigen test with serial testing in individuals is described in the following Table.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)

10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	
1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.						
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.						
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.						

Clinical performance characteristics of iHealth® COVID-19 Antigen Rapid Test was evaluated in a total of five (5) investigational sites throughout the U.S. A total of 139 individuals with signs and symptoms of COVID-19 within the first seven (7) days of symptom onset completed the study and obtained a valid result. Each Subject was provided a iHealth® COVID-19 Antigen Rapid Test. Under the observation of a clinical site staff member trained as a proctor, subjects fifteen (15) years and older independently collected an anterior nasal sample, conducted the test, interpreted and reported their self-test result. The parents of subjects two (2) to fourteen (14) years of age collected the anterior nasal sample, conducted the test, interpreted and recorded the test result for the child. The iHealth® COVID-19 Antigen Rapid Test results were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. The iHealth® COVID-19 Antigen Rapid Test when conducted by a lay user correctly identified 94.3% of positive samples. Additionally, the iHealth® COVID-19 Antigen Rapid Test correctly identified 98.1% of negative samples. The performance is shown in the following table.

iHealth® COVID-19 Antigen Rapid Test	Comparator Method		
	Positive	Negative	Total
Positive	33	2[b]	35
Negative	2[a]	102	104
Total	35	104	139
Positive Agreement: (33/35) 94.3%; 95% Confidence Interval: 81.4% to 98.4%			
Negative Agreement: (102/104) 98.1%; 95% Confidence Interval: 93.3% to 99.5%			
[a] Of the 2 false negative samples, one was positive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, the other one was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay. [b] Of the 2 false positive samples, one was negative on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay, the other was inconclusive on a second FDA EUA high sensitivity molecular SARS-CoV-2 assay.			

2 samples generated an invalid COVID-19 Antigen Rapid Test result.

Age and gender distribution and positive rate of symptomatic subjects within first 7 days of symptom onset

Age Group (years)	Female	Male	Positive	Positivity Rate % (total positive/total tested)
2 to 13	6	8	3	21.4% (3/14)
14 to 24	15	12	3	11.1% (3/27)
25 to 64	46	44	28	31.1% (28/90)
≥65	5	3	1	12.5% (1/8)
Total	72	67	35	25.2% (35/139)

Positive results broken down by days since symptom onset				
Days Since Symptom Onset	RT-PCR Positive (+)	iHealth test Positive (+)	PPA	95 % Confidence Interval
1	1	1	100.0%	20.7% - 100.0%
2	3	3	100.0%	43.8% - 100.0%
3	3	2	66.7%	20.8% - 93.9%
4	5	5	100.0%	56.6% -100.0%
5	12	12	100.0%	75.7% - 100.0%
6	6	6	100.0%	61% - 100.0%
7	5	4	80.0%	37.6% - 96.4%
All specimens	35	33	94.3%	81.4% - 98.4%

Additional asymptomatic individuals and individuals beyond the seven days of symptom onset were tested, but excluded from the primary performance calculations because they were not included in the intended use. A higher proportion of low positive specimens were observed in these populations, resulting in PPAs between of 85-88% in these individuals.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LOD)

The LOD of iHealth® COVID-19 Antigen Rapid Test was established by using limiting dilutions of heat inactivated SARS-CoV-2 virus(USA-WA1/2020) sample. The strain was spiked into clinical matrix prepared by mixing raw nasal fluid in saline and confirmed again as SARS-CoV-2 negative by RT-PCR.

The estimated LoD found from the initial 4 different concentrations test by testing 5 replicates. At each dilution, 17.5 µL samples were added to swabs and then tested through the full assay workflow, from processing in the extraction reagent to read test result.

A concentration was chosen between the last dilution to give five positive results and the first to give five negative results. Using this concentration, the LoD was further refined with a 2-fold dilution series. The LOD was determined as the lowest virus concentration that was

detected ≥ 95% of the time (concentration at which at least 19 out of 20 replicates tested positive).

The iHealth® COVID-19 Antigen Rapid Test LOD in natural nasal swab matrix is 20×10^3 $TCID_{50}$/mL. Based upon the testing procedure for this study, the LoD of iHealth® COVID-19 Antigen Rapid Test $TCID_{50}$/mL equates to 350 $TCID_{50}$/swab.

Cross Reactivity (Analytical Specificity) and Microbial Interference

The potential cross-reactivity (exclusivity) of a panel of common organisms was evaluated with SARS-CoV-2 negative samples using the iHealth® COVID-19 Antigen Rapid Test. Potential microbial interference was evaluated with samples containing heat inactivated SARS-CoV-2 virus(USA-WA1/2020) sample at approximately 3 x LoD.

A total of 38 commensal and pathogenic microorganisms (13 bacteria and 25 viruses) that may be present in the nasal cavity were evaluated in this study. Each of the organism and viruses were tested in five replicates in the absence or presence of heat inactivated SARS-CoV-2 virus.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below.

List of Organism		Concentration tested	Cross-reactivity results	Microbial Interference results
Other high priority pathogens from the same genetic family	Human coronavirus 229E	3.74×10^4 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus OC43	2.51×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Human coronavirus NL63	1.36×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	MERS-coronavirus	1.36×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
High priority organisms likely in the circulating area	Adenovirus Type 1	2.04×10^7 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 4	2.09×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 7A	2.04×10^7 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 8	1.13×10^5 $TCID_{50}$/mL	No cross-reactivity	No interference
	Adenovirus Type 31	1.13×10^5 U/mL	No cross-reactivity	No interference
	Adenovirus Type 41	9.36×10^4 $TCID_{50}$/mL	No	No

			cross-reactivity	interference
	Human Metapneumovirus 3(hMPV-3) Type B1	$3.11\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Human Metapneumovirus 4(hMPV-4) Type B2	$5.25\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Human Metapneumovirus 9(hMPV-9) Type A1	$9.36\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 1	$6.30\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 2	$7.55\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 3	$2.29\times10^{6}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 4A	$4.50\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Parainfluenza Virus Type 4B	$1.36\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Influenza A H3N2 Virus	$1.13\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Influenza B Virus	$3.74\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Enterovirus Type 68	$7.55\times10^{5}TCID_{50}/mL$	No cross-reactivity	No interference
	Enterovirus Type 71	$2.29\times10^{6}TCID_{50}/mL$	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type A (RSV-A)	$1.90\times10^{6}TCID_{50}/mL$	No cross-reactivity	No interference
	Respiratory Syncytial Virus Type B (RSV-B)	$3.74\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Rhinovirus Type 1A	$9.36\times10^{4}TCID_{50}/mL$	No cross-reactivity	No interference
	Haemophilus influenzae	$6.75\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Streptococcus pneumoniae	$1.80\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Streptococcus pyogenes	$2.04\times10^{9}CFU/mL$	No cross-reactivity	No interference
	Candida albicans	$3.15\times10^{8}CFU/mL$	No cross-reactivity	No interference
	Pooled human nasal wash – representative of normal respiratory microbial flora	-	No cross-reactivity	No interference
	Bordetella pertussis	$3.22\times10^{9}CFU/mL$	No cross-reactivity	No interference

	Mycoplasma pneumoniae	1.35×10^{8}CFU/mL	No cross-reactivity	No interference
	Chlamydia pneumoniae	8.65×10^{7}IFU/mL	No cross-reactivity	No interference
	Legionella pneumophila	7.10×10^{9}CFU/mL	No cross-reactivity	No interference
	Staphylococcus aureus	3.23×10^{9}CFU/mL	No cross-reactivity	No interference
	Staphylococcus epidermidis	1.24×10^{9}CFU/mL	No cross-reactivity	No interference
	Mycobacterium tuberculosis	1.15×10^{8}CFU/mL	No cross-reactivity	No interference
	Pneumocystis jirovecii (PJP)	3.17×10^{8}CFU/mL	No cross-reactivity	No interference

An in-silico analysis was performed using the Basic Local Alignment Search Tool (BLASTp) managed by the National Center for Biotechnology Information (NCBI) for Human Coronavirus HKU1, Mycobacterium tuberculosis, Pneumocystis jirovecii and SARS-CoV-1

- Human Coronavirus HKU1 shows 36.74% homology across 82% of the nucleocapsid sequence(see Annex 2 and 3), which is relatively low. However, cross-reactivity cannot be ruled out.
- *Mycobacterium tuberculosis* shows no protein sequence homology with nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.
- *Pneumocystis jirovecii* shows no protein sequence homology with nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.
- SARS-CoV-1 shows 90.52% homology across 100% of the nucleocapsid sequence. Therefore, cross-reactivity is highly likely.

Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the iHealth® COVID-19 Antigen Rapid Test.

The SARS-CoV-2 target concentration in the positive samples was approximately 3 x LoD. All samples tested in 5 replicates produced expected results, demonstrating that the iHealth® COVID-19 Antigen Rapid Test performance was not affected by any of the 26 potentially interfering substances listed in the table below at the concentrations tested.

Substance	**Concentration in negative/positive**	**Cross-reactivity**	**Interference**

	sample		
Whole Blood	4%	No cross-reactivity	No interference
Mucin	0.5%	No cross-reactivity	No interference
Chloraseptic (Menthol)	1.5 mg/mL	No cross-reactivity	No interference
Chloraseptic (Benzocaine)	1.5 mg/mL	No cross-reactivity	No interference
Naso GEL (NeilMed)	5% v/v	No cross-reactivity	No interference
CVS Nasal Drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference
CVS Nasal Spray (Cromolyn)	15% v/v	No cross-reactivity	No interference
Zicam	5% v/v	No cross-reactivity	No interference
Homeopathic (Alkalol)	1:10 dilution	No cross-reactivity	No interference
Sore Throat Phenol Spray	15% v/v	No cross-reactivity	No interference
Tobramycin	4 µg/mL	No cross-reactivity	No interference
Mupirocin	10 mg/mL	No cross-reactivity	No interference
Fluticasone Propionate	5% v/v	No cross-reactivity	No interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No cross-reactivity	No interference
Nasocort Allergy 24 hour(Triamcinolone)	15% v/v	No cross-reactivity	No interference
NeilMed SinuFlow Ready Rinse(Sodium chloride, Sodium bicarbonate)	15% v/v	No cross-reactivity	No interference
NeilMed SinuFrin Plus(Oyxmetazoline HCl)	15% v/v	No cross-reactivity	No interference
Neo-Synephrine (Phenylephrine ,hydrochloride)	15% v/v	No cross-reactivity	No interference
Rhinocort (Budesonide /Glucocorticoid)	15% v/v	No cross-reactivity	No interference
Saline nasal spray (Saline)	15% v/v	No cross-reactivity	No interference
Zanamivir	282.0 ng/mL	No cross-reactivity	No interference
Biotin	1.0 µg/mL	No cross-reactivity	No interference
Laundry Detergent (C12-15 pareth-7 and sodium laureth-12 sulfate)	1% v/v	No cross-reactivity	No interference
Dish-washing Liquid (Sodium lauryl sulfate)	1% v/v	No cross-reactivity	No interference
Bleach (Sodium Hypochlorite)	1%v/v	No cross-reactivity	No interference

Hook Effect

No high dose hook effect was observed when tested with a concentration of 1.15x 10^7

$TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the iHealth® COVID-19 Antigen Rapid Test .

Usability Study

iHealth conducted a study to evaluate whether a home user can follow instructions provided and can successfully perform the test steps for the iHealth® COVID-19 Antigen Rapid Test, including nasal swab collection, adding sample to a test card, and correctly interpreting the results.

105 lay users, including self-collection (n=52) and collection for other lay user (n=53), participated in the study, and were instructed to self-collect or collect a sample from others (include children), complete the required procedural steps, and interpret the test results unassisted in a simulated home setting. After the simulated test, all the participants completed the knowledge assessment questionnaire and usability questionnaire.

The overall success of every task completed by all subjects enrolled was determined by unassisted professional observation. Subjects performed 96.8% (718/742) of steps/tasks correctly, and performed 98.1% (1414/1442) of knowledge assessment questionnaires correctly. More than 90% of all the participants stated the device is easy to use, including sample collection, performing the test, reading and understanding the result. 94.29% of the participants stated the instructions provided were easy to read and understood.

The sponsor also conducted additional usability study on how to prepare material when lay user obtain Test Set 2 of the iHealth COVID-19 Antigen Rapid Test . A total of 35 lay users participated in this study, 18 of them were guided by paper IFU and 17 of them were guided by APP. Subjects performed 100% (105/105) of steps/tasks correctly, and performed 97.7% (171/175) of questionnaires correctly.

Flex study

The robust use of iHealth® COVID-19 Antigen Rapid Test was demonstrated by ten (10) Flex studies: delay in result reading, extraction liquid volume variability, swab mixing expression variability, temperature and humidity, impact of light sources, test device held at different orientation and disturbance during analysis.

CUSTOMER HELPLINE

If you have any questions about the iHealth® COVID-19 Antigen Rapid Test or your result, please contact our toll-free Customer Helpline on 1-855-816-7705.

SYMBOLS IN USE

Caution

Do not Reuse

Consult Instructions for Use

In Vitro Diagnostic Medical Device

Storage Temperature Limitation

Keep in a dry place

Keep away from direct sunlight

Do not use if package is damage

Manufacturer

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